REMARKS

As a preliminary matter, the undersigned has previously submitted a PTO Form SB/81 (Revocation of Power of Attorney/New Power of Attorney), empowering the undersigned and his firm to take action in the present application. The required Statement under 37 CFR 3.73(b) has also been submitted. The undersigned also expresses his appreciation for the courtesy shown by Examiner Rogers during the brief telephone interview held on Feb. 4, 2010. During that interview, no claims or prior art references were discussed. The sole topic discussed was to confirm that the most recent Action issued by the Office is indeed a non-final Action, which the Examiner confirmed. The present paper is responsive to that non-final Action.

Claim 33 is amended to delete the limitation objected to by the Examiner in the previous Office Action, and to include the term "composite" in the preamble for consistency with the remaining claims. Claim 41 is amended to correct a minor typographical error. These amendments to claims 33 and 41 introduce no new matter. New claim 66 includes the limitation of a pH-sensitive mucoadhesive layer comprising at least one anionic pH-sensitive film-forming copolymer of methacrylic acid and acrylic or methacrylic ester. This amendment simply combines the limitations of current claims 33 and 39. Therefore, no new matter is added.

A. THE REJECTION OF CLAIMS UNDER 35 U.S.C. §112, 1ST PARAGRAPH IS BELIEVED TO BE OVERCOME.

The Examiner rejects claims 33-34, 36-46, 51, 57, and 63-64 as failing to comply with the written description requirement. Specifically, the Examiner objects to inclusion of the limitation of a pH-sensitive mucoadhesive layer that is free of any natural polymers and free of any neutral polymers. That limitation is removed by the present amendment, and therefore this portion of the rejection is believed to have been satisfactorily addressed.

The Examiner also objects to the limitation concerning "anionic pH-sensitive film forming polymers." Respectfully, express support is set forth in the present Specification for this limitation. The Examiner's attention is directed at least to *page 16, ll 19-23*, wherein there is recited "Examples of pH-sensitive film-forming polymers that meet

these criteria are, but not limited to, Eudragits® and cellulose acetate phthalate polymers, or derivatives thereof. Eudragits® are synthetic cationic and anionic polymers of methacrylic acid and methacrylic acid esters in varying ratios" (emphasis added). Thus, support is found in the present specification for both cationic and anionic pH-sensitive film-forming polymers. The fact that the Applicant elects to claim only anionic pH-sensitive film-forming polymers in the present application, and to defer consideration of claiming other described polymers such as cationic pH-sensitive film-forming polymers to a subsequent progeny patent application, has no bearing on the analysis under Section 112.

The case law regarding Section 112, 1st paragraph is consistent in holding that it is sufficient if the originally filed disclosure would have conveyed to one having ordinary skill in the art that the inventor had possession **of the concept** of what is claimed.[1]. Newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.[2] It is believed that full support for the disputed limitation is present in the Specification. Even if this were not the case, *In re Anderson* stands for the proposition that even a term appearing nowhere in the specification can be added to a claim without constituting new matter as long as the **concept** of what is being claimed is present in the original disclosure. Here, at the least the concept, if not the specific limitation, is presented in the Specification and the *In re Anderson* standard is clearly met. This portion of the rejection is believed also to have been satisfactorily addressed.

The Examiner also objects to the claim 63 limitation concerning Noveon:Eudragit ratios between about 2:1 to about 4:1, but admits that specific examples of ranges of 2:1, 3:1, and 4:1 are presented. As stated in the MPEP, "... this analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure."[3] In the present case, ranges are expressly disclosed in the Specification which are not so far apart as to cause the skilled artisan to question whether the intervening ratios were contemplated. This is not the case where upper, middle, and lower limits are disclosed which represent such a gap as to allow for near-infinite intervening possibilities, whereby claiming the range between the upper and

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[1] *In re Anderson*, 471 F.2d 1237, 176 USPQ 331(CCPA1973).

[2] Manual of Patent Examining Procedure §§2163, 2173.05(i)

[3] MPEP §2163.05, *at pg. 2100-190.*

lower ratios violates the written description requirement. That is, the skilled artisan in this field, presented with the specific examples of ratios of 2:1, 3:1, and 4:1, would consider a range of from about 2:1 to about 4:1 at least inherently described. It is believed that Section 112 does not require specific examples of the fractional increments between the presently discussed ratios, since the upper, lower, and middle ratios are expressly disclosed. This portion of the rejection is believed also to have been satisfactorily addressed.

Summarizing, it is believed that the foregoing amendment to claim 33, and the arguments set forth above, address the Section 112 rejection. Reconsideration is respectfully requested.

B. THE REJECTION OF CLAIMS 33-34, 36-37, 42-46, 56-57, AND 64 UNDER 35 U.S.C. §103(A) OVER SLAVTCHEFF AND SUZUKI IS BELIEVED TO BE OVERCOME.

The Examiner takes the position that the above claims are obvious over the teachings of Slavtcheff in view of Suzuki. It is believed that the foregoing amendments address this concern.

Specifically, Slavtcheff teaches adhesive cosmetic strips (see *Abstract*) including a flexible water soluble substrate, an adhesive composition deposited onto the substrate, a liquid crystal thermochromic substance, and an agent interactive with water to ensure a specified temperature rise. Nowhere does Slavtcheff expressly teach or hint at use of a *mucoadhesive* layer, much less the water-insoluble swellable anionic mucoadhesive polymer expressly claimed herein. Rather, Slavtcheff exclusively contemplates adhesives for securing its color-changing cosmetic strip (see *Col. 1, ll 61-63*) to skin surfaces (*Col. 3, ll 1-4*). This is needed for a primary function of the dermal strip of Slavtcheff, that is, for the adhesive to dry over the area of treatment whereby keratotic plugs adhere to it (*Col. 5, ll 18-24*). There is no indication in Slavtcheff of any need for a mucoadhesive polymer, which is to be expected since Slavtcheff does not contemplate use of its cosmetic dermal strip on mucosal surfaces but rather solely on skin.

Not only does Slavtcheff lack any hint of a mucoadhesive layer, Slavtcheff provides no teaching, nor is there any indication that Slavtcheff at all contemplates, a *pH-sensitive* mucoadhesive layer as is expressly claimed herein. Rather, Slavtcheff expressly

recites a *temperature-sensitive* adhesive layer comprising liquid crystal thermochromic substances (*Col. 2, ll 25-65*) wherein a water-interactive agent induces a temperature change of at least 2 ° C (*Col. 2, ll 15-17*) which causes the thermochromic substances to change color to provide a visual indicator to the consumer that the dermal strip has been in place for a sufficient period of time. There is simply no indication in Slavtcheff of any need for a pH-sensitive mucoadhesive polymer, which is to be expected since Slavtcheff relies exclusively on temperature changes for its recited and claimed color-changing function.

The Examiner cites Suzuki for teachings of thin layers for adhesive patches and for use of a wax backing layer. This may be the case, but even assuming this to be so the defect in Slavtcheff as a Section 103 reference is not cured, and the *prima facie* case for obviousness is not supported. Further, as is the case for Slavtcheff, Suzuki simply does not teach or otherwise contemplate a ph-sensitive mucoadhesive layer as is expressly claimed herein, comprising at least one anionic pH-sensitive mucoadhesive polymer. Rather, Suzuki teaches only a covering material *consisting essentially* of a cellulose lower alkyl ether and a polyacrylic acid or pharmaceutically acceptable salt thereof (emphasis added, see *Abstract*). Thus, in its recitation of "consisting essentially of a cellulose lower alkyl ether and a polyacrylic acid," Suzuki expressly excludes consideration of the presently claimed pH-sensitive mucoadhesive polymer and of the anionic pH-sensitive film-forming polymer.[4] Likewise, Suzuki excludes the composition recited in new claim 66, including a pH-sensitive mucoadhesive layer comprising at least one anionic pH-sensitive film-forming copolymer of methacrylic acid and acrylic or methacrylic ester. Even further, in a prior action dated 12/23/2008, the Office conceded that Suzuki did not teach specific film formers as recited in the present independent claims (see the 12/23/2008 Action, at page 6).

Even more, it is respectfully reiterated that Suzuki would not be considered by the skilled artisan, in that a teaching away from a bi-layer wax-film composite comprising at least one molecule of interest (as expressly claimed herein) is provided by Suzuki. Suzuki requires a "covering material *consisting essentially* of a cellulose lower alkyl

[4] *See*, MPEP §2111.03, noting that the transitional phrase "consisting essentially of" is interpreted to be limiting to those materials or steps that do not materially affect the basic and novel characteristics of the claimed invention.

ether and a polyacrylic acid or its pharmaceutically acceptable salt," and goes on to include a further limitation of not containing a medicament (see *Col. 2, ll 4-11*; *see also* Claim 1 of Suzuki reciting a medicament-free adhesive layer and a medicament-free nonadhesive layer). Indeed, Suzuki teaches only a medicament-free composition, and does not even contemplate whether its composition could even be capable of delivering a medicament. A reference teaches away when the person of ordinary skill, upon reading the reference, is discouraged from following the path set out in the reference, or would be led in a divergent direction from the path taken by the applicant.[5] Thus, it is believed that the teachings of Suzuki would have discouraged the skilled artisan from following the path set out in Suzuki, or would have been led in a divergent direction from the path taken by the present Applicant.

The *prima facie* case of obviousness is established only when the teachings from the prior art, the knowledge available to the skilled artisan, or a combination thereof would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. [6] Also, despite any recent revisions to the MPEP, it remains a requirement to a finding of obviousness that the prior art reference or references must teach or suggest all the claim limitations.[7] This test for *prima facie* obviousness is consistent with the legal principles set forth in *KSR Int'l Co. v. Teleflex Inc.*[8] Summarizing the Supreme Court's holding in that case, the Federal Circuit Court of Appeals noted that "... the Court acknowledged the importance of identifying 'a *reason* that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination."[9] When determining whether a claim is obvious, an Examiner must make "a searching comparison of the claimed invention - *including all its limitations* - with the teaching of the prior art."[10]

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[5] *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

[6] *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir.1993).

[7] Manual of Patent Examining Procedure §2143.

[8] *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007).

[9] *Takeda Chemical Industries Ltd. v. Alphapharm Pty.*, 83 USPQ2d 1169 (Fed. Cir. 2007) (quoting *KSR*, 127 S. Ct. at 1731).

[10] *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

Moreover, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."[11]

In rejecting claims under Section 103 it is the Examiner's initial burden to present a *prima facie* case for obviousness.[12] Slavtcheff fails to teach, expressly or inherently, a mucoadhesive layer as expressly claimed herein. Even more, Slavtcheff provides no teaching, express or inherent, of a *pH-sensitive* mucoadhesive layer. Suzuki, by its recitation of an adhesive "consisting essentially of a cellulose lower alkyl ether and a polyacrylic acid or pharmaceutically acceptable salt thereof," expressly excludes the pH-sensitive mucoadhesive layer as claimed herein, that is, comprising at least one anionic pH-sensitive film-forming polymer. Still yet further, Suzuki teaches away from the presently claimed limitation of inclusion of a molecule of interest. Therefore, it is believed that neither Slavtcheff, Suzuki, nor any reasonable combination thereof teach or suggest each and every limitation of the present independent claims, nor is any reason articulated that would lead the skilled artisan to combine the references. Accordingly, the *prima facie* case of obviousness has not been properly supported as to the independent claim, and the rejection must fall. Likewise, the claims depending from claim 33 are believed to be in condition for allowance without consideration of obviousness.[13] Reconsideration of the rejection over Slavtcheff and Suzuki is respectfully requested.

C. THE REJECTION OF CLAIMS 33-34, 36-46, 51, 56, 57, 63 AND 64 UNDER 35 U.S.C. §103(A) IS BELIEVED TO BE OVERCOME.

The Examiner takes the position that the above claims are obvious over the teachings of Slavtcheff in view of Suzuki, further in view of Mantelle. It is believed that the foregoing amendments address this concern. Reiterating the foregoing discussion, Slavtcheff as a primary reference fails to teach, expressly or inherently, at the least inclusion of a mucoadhesive layer as expressly claimed herein. Even more, Slavtcheff

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[11] *KSR Int' lCo. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

[12] *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

[13] *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious"); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

provides no teaching, express or inherent, of a *pH-sensitive* mucoadhesive layer. Suzuki expressly excludes such a pH-sensitive mucoadhesive layer by its use of the transitional phrase "consisting essentially of." Still yet further, Suzuki teaches away from the presently claimed limitation of inclusion of a molecule of interest by its express recitation of a composition for curing *without* use of a medicament without contemplating any alternative formulation including a medicament, or without any indication that its composition for curing without a medicament might even be capable of delivering a medicament.

Mantelle is cited for a teaching of "use of Noveon® and Eudragit® polymers in adhesive compositions for personal use" (page 6 of the recent Action). However, nowhere in Mantelle is any teaching or reason for the skilled artisan to consider combining Mantelle with any teaching of Slavtcheff or Suzuki to arrive at a pH-sensitive mucoadhesive layer comprising at least one anionic pH-sensitive film-forming polymer.

The trade name Eudragit® is applied to a range of different polymers having a range of properties, and thus the Examiner's mere recitation of the trade name Eudragit® as used in Mantelle does not and cannot rise to the level of a teaching sufficient to provide the skilled artisan a reason to consider combining the teachings of Mantelle with those of Slavtcheff and/or Suzuki. Indeed, in the present case it is believed that Mantelle would expressly lead the skilled artisan away from such a combination. The Examiner's attention is directed to *Col. 38, ll 1-6* of Mantelle, wherein are recited particular acrylic adhesives believed to be suitable for the Mantelle compositions. It is believed to be this portion of Mantelle on which the Examiner relies for the recitation of a Eudragit®. In that section of Mantelle, it is noted that specifically Eudragit® RL and RS, and no others, are set forth as meeting Mantelle's specification for useful acrylic adhesives.

A brief review of the information provided by the manufacturer of the Eudragit® line of polymers shows that Eudragit® RS and RL refer to polymers which are insoluble and whose swelling properties are pH-insensitive (see **Exhibit 1** appended hereto). Thus, to the extent that the teachings of Mantelle would lead the skilled artisan to consider a Eudragit® polymer, it would be a pH-*insensitive* polymer to which Mantelle would lead that artisan. In total contrast, claim 33 of the present disclosure expressly requires a pH-*sensitive* film-forming polymer. Mantelle would <u>not</u> motivate the skilled artisan to

consider a Eudragit polymer to provide a pH-sensitive film-forming copolymer. Stated differently, Mantelle provides no reason leading the skilled artisan to consider Eudragit® to arrive at the presently claimed combination.

No combination of Slavtcheff, Suzuki, or Mantelle teaches each and every limitation of the present independent claims. Likewise, no teaching of the references, express or inherent, provides any articulated reason leading the skilled artisan to combine the references to achieve the presently claimed combination, and the independent claims are believed to be in condition for allowance under the propositions set forth by *In re Ochiae* and *KSR Int'l*. The dependent claims are likewise believed to be allowable without consideration of obviousness under the proposition set forth in *In re Fritch* and *In re Fine*. Reconsideration of the rejection, and allowance of the claims, is respectfully requested.

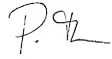
D. CONCLUSION

All pending issues and all rejections of record are believed to have been overcome. Therefore, issuance of a prompt Notice of Allowance for the pending claims of the present application is believed to be merited and is respectfully requested. Also, in the Office Action mailed on 02/02/3004, the Examiner required restriction to a number of species relating to the claim limitation of "at least one molecule of interest." In that Action, the Examiner stated that "a claim for 'a wax-film composite' is generic" to those species. Since it is believed that the generic claim (claim 33) to the wax film composite is in condition for allowance, rejoinder and allowance of claims 48-50 and 53-55 depending therefrom is also respectfully requested.

This paper is filed concurrently with an extension of time of one (1) month, tolling the response deadline to **February 9, 2010**. The Commissioner is authorized to deduct the required fee from the undersigned representative's **Deposit Account No. 11-0978.**

Respectfully submitted,

KING & SCHICKLI, PLLC



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EUDRAGIT® RS PO	Powder	
EUDRAGIT® RS 30 D	30% Aqueous Dispersion	
EUDRAGIT® RS 12,5	12,5% Organic Solution	
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Exhibit 1